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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/235,986	01/22/1999	WAYNE A. HENDRICKSON	58323/JPW/PT	2152

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JOHN P WHITE
COOPER & DUNHAM LLP
1185 AVENUE OF AMERICAS
NEW YORK, NY 10036

EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/235,986

Applicant(s)

HENDRICKSON ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/7/05 has been entered.

Applicant's arguments filed 2/7/05 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-13 are under consideration by the examiner.

Claim Rejections - 35 USC § 112

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 has been amended to recite "said database including a controller for updating said database with additional information."

The only basis pointed to for this claim amendment s is page 13, line 31, through page 14, line 1. Note that Figure 1 and page 13, line 31, through page 14, line 1, clearly demonstrate

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that the controller is not part of the database. The box labeled “1” is the “system component” and has two SEPARATE parts, a database (1a) and a controller (1b). Figure 1 limits the database of 1a to a genomics database and the controller of 1b to a control apparatus. Thus, there is no basis for a database that “includes a controller for controlling generation and update of the database.” Claim 1 and its dependent claims contain new matter.

Claim 13 is a newly introduced claim. Basis is stated to be at page 10, line 29, through page 12, line 4. However, the method and steps set forth in claim 13 do not correspond to the method set forth at these pages. See in particular step (a)-(d), (g), and (j)-(m).

Applicant is requested to point to basis for EACH and EVERY limitation of the amended claims as none is apparent.

Claims 1-12 remain new matter for the reasons set forth in the prior Office actions as well.

Again, a fair reading of the specification as originally filed would not convey to one of ordinary skill in the art that what is now claimed was the contemplated invention. **Applicant may not recast or repackage the system components and method steps originally contemplated into different combinations after the fact. The presently claimed methods as written are conceptually different from those claims originally filed and the methods disclosed in the specification as filed.** They constitute new matter. The examiner does not see basis in the charts or arguments of record for the claimed system (claims 1-6) having claimed the database, at least one bioinformatics tool, protein synthesis means, protein processing means, crystallization means, X-ray crystallography means, analyzing means, structure extraction means, homology model building tool, and cryoprotection means (claim 2) having all of the

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limitations as set forth in the claims. The examiner does not see basis in the charts or arguments of record for the claimed process having steps (a)-(j) (claims 7-12). Comparison of independent claims 1 and 7 alone to the basis pointed to in applicant's chart reveals that basis for the system of claim 1 is premised on Figure 1 and pages 12-16 and 20-21 of the specification and that basis for the process of claim 1 is premised on pages 10-16 and 20-22 of the specification. The system components and method steps set forth here neither match those of the claims in a broad sense or in particulars.

Claim Rejections - 35 USC § 112

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some aspects of the claimed method and system, does not reasonably provide enablement for the breadth of what is encompassed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is maintained with for reasons of record with respect to claims 1-12 and newly applied to claim 13 for the same reasons.

One of ordinary skill in the art is not guided to what system to make and how the parts are interrelated or connected. Likewise, without clear guidance as to how the system is set up, one of ordinary skill in the art is not guided as to how to perform the claimed process.

As set forth in the prior Office actions, claims 1-6 are considered to encompass an integrated (in some unidentified fashion), turn-key system and/or fully automated system that is not enabled. An adequate disclosure of a device requires details of how complex components are

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constructed and perform the desired function, particularly if the specification does not detail how the parts should be interconnected and controlled. Block diagrams with functional labels do not indicate whether the parts are “off the shelf” or must be specifically constructed or modified for applicant’s system. See MPEP 2164.06(a).

There is no argument nor evidence of record that such synchrotron facilities would permit physical, structural, or functional connection with any or all of the devices set forth in the claims.

Applicant is requested to explicitly set forth on the record what they believe the claimed system is directed to with respect to integration of components or lack thereof.

Reference to generic off the shelf programs at page 16 of the response does not provide guidance to one of ordinary skill in the art as to what system to build or how. Naming different devices without guidance as to how the parts should be interconnected and controlled is not enabling. Applicant presents arguments with respect to prior art. This is not germane to building the claimed system. Applicant is requested to document the assertion on page 16 that one skilled in the art with the suggestions and guidance provided by this application would readily be able to implement such robotics and automation processes. The examiner is not aware of any systems having all of the means required by the claims integrated and or automated in this way. Furthermore, the claims do not contain limitations to robotics or automation.

It is unclear what the computer printouts of web pages regarding facilities at the Argonne National Laboratory (ANL) Advanced Photon Source (APS) are intended to show. Submitting proposals or communicating data to and from the APS are not limitations of the claims. These

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pages do not document enablement of a system or process using such a system as claimed by applicant.

Applicant's response fails to address their assertion that the claim language invokes 35 USC 112, sixth paragraph. Applicant has not pointed to the particular means specified in the written description and equivalents thereof to perform the particular function. It does not appear that the corresponding structure, material, or acts are set forth in the written description necessary to perform the function. Applicant is reminded that upon appeal they will be required to identify every means plus function and set forth every structure, material, or act described in the specification as corresponding to each claimed function.

With respect to claims 7-12 and newly applied to claim 13, the specification fails to guide one of skill in the art as to the particular steps to be performed and how they are to be performed in order to execute the method. For example, claim 7 recites "using at least one bioinformatics tool and the sequence information, structural information and functional information stored in the database." This does not illuminate which bioinformatic tool, what specific information, or how to use it to achieve the goal of clustering. It does not provide the positive, active steps to perform on unspecified structural or sequence information to arrive at a plurality of families within the context of the claims. For example, the database has sequence information for a first plurality of proteins and structural information and functional information for a second plurality of proteins. (Note that it is unclear if this is a partitioned database for the first and second plurality as they do not contain the same types of information.) For example, say the structural information for the second plurality is polymeric structure (monomer, dimer, etc.). For example,

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say the functional information for the second plurality is enzymatic activity (protease, synthase, etc.) How does one practicing the invention use polymeric structure and enzymatic activity to cluster into a plurality of families? For example, proteins A, B, and C are in the first plurality and proteins D, E, and F are in the second plurality. Protein D is a monomeric protease. Protein E is a trimeric synthase. Protein F is a monomeric protease. What is the plurality of families that the at least one bioinformatics tool identifies? How are homologous sequences for the family determined if the database does not contain sequence information for D, E, and F and their sequences cannot be compared to sequence information for A, B, and C? The specification provides no discussion or guidance for adapting bioinformatics tools to make such determinations. Going further in the claim to step (g), the refined model is stored in the database. Note that part (a) does not require that the structural information include a refined model or a homology model. Going further in the claim to step (j), the database is updated to link the refined model to other databases. Note that part (a) does not require that the database have links to any information at all. The method steps as written are internally inconsistent. As written, one of ordinary skill in the art would be unable to practice the method for at least these reasons.

Likewise, claim 13 is similarly not enabled as it parallels claim 7. In addition, there is no guidance for how steps (k)-(m) are to be performed by one of ordinary skill in the art.

Applicant is reminded that claims are interpreted in view of the specification without importing limitations from the specification into the claims. As such, the specification must enable the full breadth of what is claimed not merely some aspects of the claims.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These rejections are maintained for reasons of record and newly applied to claim 13 for the same reasons as this claim recites the same “homologous sequences” and “families.”

Claim Rejections - 35 USC § 102

Claims 1-13 are rejected under 35 U.S.C. 102(a) as being anticipated because the invention was known by others in this country before the invention thereof by applicant for a patent as evidenced by the Workshop on Structural Genomics held at Argonne National Laboratories held January 1998, National Institute of General Medical Sciences (NIGMS) Protein Structure Initiative (PSI) held 4/24/98, NIGMS Genomics Project Planning Meeting held 11/24/98, Structural Genomics Meeting held October 1998 in Avalon, New Jersey, Shapiro et al. (Current Biology, 15 March 1998) and Gaasterland (Nature Biotechnology, July 1998).

This rejection is maintained for reasons of record as applied to claims 1-12 and newly applied to claim 13 for the same reason.

Claims 1-13 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter in view of the Workshop on Structural Genomics held at Argonne National Laboratories held January 1998, National Institute of General Medical Sciences (NIGMS) Protein Structure Initiative (PSI) held 4/24/98, NIGMS Genomics Project Planning

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Meeting held 11/24/98, Structural Genomics Meeting held October 1998 in Avalon, New Jersey, and Gaasterland (Nature Biotechnology, July 1998).

This rejection is maintained for reasons of record as applied to claims 1-12 and newly applied to claim 13 for the same reason.

Applicant has not presented evidence disputing the content of what was discussed at these meetings.

The documents of record pertaining to the cited meetings provide every indication that the claimed system and method were discussed in a general way and a particular way with respect to particular methodologies to practice the method to those in attendance.

Page 18 of the 4/24/98 meeting lists Paul Bash and Eaton Lattman (co-chairs and workshop participants) as the authors of the document. As they were present at the meeting, the content of the NIGMS Meeting summary reflects the knowledge of those present.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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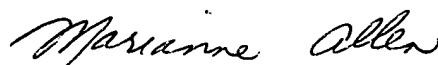
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


Marianne P. Allen
Primary Examiner
Art Unit 1631
5/31/05

mpa